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JOHN F. DAVIS, CLERK

No. 3361

Supreme Court of the United States

OCTOBER TERM, 1966

THE TOILET GOODS ASSOCIATION, INC.; ANITA D'FOGED, INC.; AVON PRODUCTS, INC.; BEAUTY COUNSELORS, INC.; BONNE BELL, INC.; BOURJOIS, INC.; CHARLES OF THE RITZ, INC.; CHESEBROUGH-POND'S INC.; CHRISTIAN DIOR PERFUMES CORP.; CLAIROL INCORPORATED; COLONIAL DAMES CO., LTD.; COTY, INC.; FABERGÉ INC.; FRANCES DENNY, INC.; THE FULLER BRUSH CO.; THE GEORGE W. LUFT CO., INC.; THE GILLETTE COMPANY; A. M. HANSEN, doing business as HOUSE OF HOLLYWOOD; HARPER METHOD, INC.; HELENA RUBINSTEIN, INC.; HELENE CURTIS INDUSTRIES, INC.; HENRY/HARAN/HUTCHINGS, INC.; HERBOLD LABORATORY, INC.; JOHN H. BRECK, INC.; KOLMAR LABORATORIES, INC.; LADY LENNOX COMPANY, INC.; LEHN & FINK PRODUCTS CORPORATION; ARNOLD L. LEWIS, doing business as STUDIO COSMETIC CO.; MAX FACTOR & CO.; MAYBELLINE CO.; MERLE NORMAN COSMETICS, INC.; JACK B. NETHERCUTT, doing business as NETHERCUTT LABORATORIES; NEUTROGENA CORP.; NUTRILITE PRODUCTS, INC.; OLD 97 COMPANY; PRIVATE LABEL COSMETICS CO., INC.; PURITAN COSMETICS CO.; REVLON, INC.; ROUX LABORATORIES, INC.; SHULTON, INC.; and YARDLEY OF LONDON, INC., *Petitioners,*

v.

JOHN W. GARDNER, Secretary of Health, Education and Welfare, and JAMES L. GODDARD, Commissioner of Food and Drugs, *Respondents.*

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT.

EDWARD J. ROSS
One Chase Manhattan Plaza
New York, New York 10005
Attorney for Petitioners

Of Counsel:

BREED, ABBOTT & MORGAN
One Chase Manhattan Plaza
New York, New York 10005

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JOHN W. GARDNER, Secretary of Health, Education and Welfare, and JAMES L. GODDARD, Commissioner of Food and Drugs, *Respondents*.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT.

Petitioners pray that a writ of certiorari issue to review that portion of the judgment of the United States Court of Appeals for the Second Circuit which reversed the order of the District Court as to the Fourth Count of the complaint, with instructions to grant the motion to dismiss.

Opinions Below.

The opinion of the Court of Appeals, reported at 360 F.2d 677, is in Appendix A (p. 1a, *infra*). The first opinion of the United States District Court for the Southern District of New York, reported at 235 F. Supp. 648, is in Appendix B (p. 21a). The second opinion of the District Court, as yet unreported, which is the decision from which the appeal to the Court of Appeals was taken, is in Appendix C (p. 30a).

Jurisdiction.

The judgment of the Court of Appeals is dated April 13, 1966, was entered on that date and is in Appendix D (p. 36a). The jurisdiction of this Court is invoked under 28 U. S. C. §1254(1).

Questions Presented.

I.

Whether the legality of a final agency regulation for the enforcement of a statute can be determined by the District Court under the Declaratory Judgment Act, in an action brought by a substantial number of members of the cosmetic industry, who account for approximately 90% of the sales of such industry, where:

(a) the regulation grants the agency power and authority which it had sought from Congress in agency

sponsored legislation, namely, free access by the agency to the formulas and processes of cosmetics, but which Congress, after committee hearings, determined to withhold;

(b) the regulation has a practical impact and effect on the members of such industry, including exposure of valuable trade secrets, and such members are adversely affected and aggrieved by the agency action;

(c) the regulation is challenged as in excess of the agency's statutory authority and not in accordance with law;

(d) non-compliance with the regulation could cause the cosmetics to be banned from the market and, if thereafter sold, entail civil and criminal prosecution, seizure proceedings and harmful administrative actions; and

(e) the regulation was issued under a section of a statute which preserves judicial review by any method provided by law, and Congress had emphasized its intent that the Court have broad jurisdiction to review the agency's regulations.

II.

Whether the legality of such final agency regulation can be determined by the District Court under the Administrative Procedure Act.

The questions presented are of the same general character as those presented by the petition for a writ of certiorari to the United States Court of Appeals for the Third Circuit, granted on February 28, 1966, in *Abbott Laboratories* v. *Celebrezze* (No. 39)*,—a case involving other regulations of the same agency issued under the same

* The case was originally designated as No. 824, October Term, 1965 (34 LW 3289), but has been redesignated No. 39, October Term, 1966.

statute here involved. However, as shown below (pp. 17-18, *infra*), there are basic differences between the two cases which warrant the granting of this petition for a writ and hearing both cases together, rather than merely allowing this Court's decision in the *Abbott Laboratories* case perhaps to become determinative of the issues in the case at bar.

Statutes and Regulations Involved.

Statutes:

Declaratory Judgment Act, 28 U. S. C. §2201:

"§2201. Creation of remedy

"In a case of actual controversy within its jurisdiction, except with respect to Federal taxes, any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought. Any such declaration shall have the force and effect of a final judgment or decree and shall be reviewable as such."

Administrative Procedure Act, §10, 60 Stat. 243 (1946), 5 U. S. C. §1009.

"JUDICIAL REVIEW

"SEC. 10. Except so far as (1) statutes preclude judicial review or (2) agency action is by law committed to agency discretion—

"(a) RIGHT OF REVIEW.—Any person suffering legal wrong because of any agency action, or adversely affected or aggrieved by such action within the meaning of any relevant statute, shall be entitled to judicial review thereof.

"(b) FORM AND VENUE OF ACTION.—The form of proceeding for judicial review shall be any special statutory review proceeding relevant to the subject matter in any court specified by statute or, in the absence or inadequacy thereof, any applicable form of legal action (including actions for declaratory judgments or writs of prohibitory or mandatory injunction or habeas corpus) in any court of competent jurisdiction. Agency action shall be subject to judicial review in civil or criminal proceedings for judicial enforcement except to the extent that prior, adequate, and exclusive opportunity for such review is provided by law.

"(c) REVIEWABLE ACTS.—Every agency action made reviewable by statute and every final agency action for which there is no other adequate remedy in any court shall be subject to judicial review. Any preliminary, procedural, or intermediate agency action or ruling not directly reviewable shall be subject to review upon the review of the final agency action. Except as otherwise expressly required by statute, agency action otherwise final shall be final for the purposes of this subsection whether or not there has been presented or determined any application for a declaratory order, for any form of reconsideration, or (unless the agency otherwise requires by rule and provides that the action meanwhile shall be inoperative) for an appeal to superior agency authority.

* * * * * *

"(e) SCOPE OF REVIEW.—So far as necessary to decision and where presented the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of any agency action. It shall (A) compel agency action unlawfully withheld or unreasonably delayed; and (B) hold unlawful and set aside agency action, find-

> ings, and conclusions found to be (1) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law; (2) contrary to constitutional right, power, privilege, or immunity; (3) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right; (4) without observance of procedure required by law; (5) unsupported by substantial evidence in any case subject to the requirements of sections 7 and 8 or otherwise reviewed on the record of an agency hearing provided by statute; or (6) unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court. In making the foregoing determinations the court shall review the whole record or such portions thereof as may be cited by any party, and due account shall be taken of the rule of prejudicial error."

The foregoing statutory provisions govern the jurisdictional and procedural questions presented. The issue on the merits involves Section 201(t)(1) of the Federal Food, Drug, and Cosmetic Act (the "Act"), 52 Stat. 1040 (1938), as amended by Section 101(c) of the Color Additive Amendments of 1960, 74 Stat. 397, 21 U. S. C. §321(t)(1), and Section 704(a) of the Act (52 Stat. 1057), as amended by Section 201 of the Drug Amendments of 1962, 76 Stat. 792, 21 U. S. C. §374(a), which are in Appendix E (p. 38a).

Regulations:

The portion of the regulation, the validity of which is challenged by the petitioners, was promulgated by the Food and Drug Administration, Department of Health, Education and Welfare ("FDA"), and is contained in Part 8, §§8.1(f), 8.28, 21 C. F. R. §§8.1(f), 8.28 (Revised as of 1966):

> "§8.1 Definitions and Interpretations
>
> • • •

"(f) * * * A substance that, when applied to the human body results in coloring, is a 'color additive,' unless the function of coloring is purely incidental to its intended use, such as in the case of deodorants. Lipstick, rouge, eye makeup colors, and related cosmetics intended for coloring the human body are 'color additives'."

"§8.28 Authority to Refuse Certification Service.

"(a) When it appears to the Commissioner that a person has:

* * *

"(4) Refused to permit duly authorized employees of the Food and Drug Administration free access to all manufacturing facilities, processes, and formulae involved in the manufacture of color additives and intermediates from which such color additives are derived;

he may immediately suspend certification service to such person and may continue such suspension until adequate corrective action has been taken."

The full text of Sections 8.1(f) and 8.28 is in Appendix F (p. 41a).

Statement.

The basis for federal jurisdiction in the District Court is 28 U. S. C. §§1331(a) and 1337 (p. 3a; R. 21a).*

Petitioners are 40 companies which manufacture and distribute cosmetic products, and The Toilet Goods Association, Inc., an association of which these companies and other cosmetic companies are members (R. 14a-19a).

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* References to "R. 14a" or "R. 14aa," e.g., are to the pages, respectively, of the Appendix to Appellants' Brief and the Appendix to Appellees' Brief, printed for use in the Court of Appeals. Nine copies of each Appendix have been filed with the Clerk of this Court pursuant to Rule 21(4).

Each cosmetic company is directly affected by the challenged regulation involved in this petition. To remain competitive, petitioners must constantly develop new formulae and processes for cosmetics and improve existing formulae and processes. These constitute closely guarded trade secrets of substantial value.

The challenged regulation grants FDA "free access" to such secret formulae and processes, creating a substantial danger that they may be obtained by competitors. Such danger of disclosure of secret formulae and processes would discourage research and development of new products (R. 64a, R. 4aa). But apart from such danger, petitioners have an absolute right to be free of the invasion consequent on FDA's "free access" to their secret formulae and processess, unless Congress has granted such power to FDA.

As shown below, FDA had at least twice requested Congress to grant this power as to food, drugs, cosmetics and devices as necessary for enforcement of the Act (pp. 13-16, *infra*). After extensive hearings, Congress withheld the power as to cosmetics, food, devices and non-prescription drugs,—deleting the applicable clauses from the FDA sponsored legislation,—and granted it only as to prescription drugs. By the challenged regulation, FDA simply took the power as to cosmetics. The validity of FDA's arrogation of the power of "free access" to the formulae and processes of cosmetics manufactured by the petitioners is the issue as to which petitioners seek judicial review.

Proceedings Below:

The proceedings below involved four counts of the complaint, each challenging a different provision of the same regulation as in excess of FDA's statutory authority (R. 14a, 46a, 52a, 60a). Only the Fourth Count (R. 60a),

involving FDA "free access" to secret formulae and processes, is here involved since the Court of Appeals sustained reviewability of the other three regulatory provisions, directed further proceedings in the District Court as to the merits of the first three counts, and reversed the District Court only as to the fourth (p. 20a).

However, as the District Court stated, "all four challenged regulatory provisions * * * are interrelated as elements of a common plan of governmental regulation" (p. 27a). Accordingly, a brief statement of the four aspects of the regulation will place the Fourth Count in its proper context, and show the anomaly of sanctioning judicial review of three parts of a regulation and not the fourth.

The portion of the regulation challenged by the First Count of the complaint imposes a system of premarketing clearance of finished cosmetic products by requiring that cosmetic products which impart color to the human body,—substantially all cosmetics sold in the United States,—must be pretested, listed and certified by FDA before sale (R. 14a). The portion of the regulation challenged by the Second Count requires the pretesting, listing and certification, prior to sale of the finished cosmetic product, of all its non-color ingredients (R. 46a). If the product is sold without the requisite certification or if certification is suspended, the product is *ipso facto* deemed adulterated (§§601(e), 706(a) of the Act; 21 U. S. C. §§361(e), 376(a)). Sale becomes illegal, subjecting the seller to substantial criminal and civil penalties, including multiple seizures of product (§§301(a), 302(a), 303(a), 304(a)(b) of the Act; 21 U. S. C. §§331(a), 332(a), 333(a), 334(a)(b)).

It is petitioners' position that the Act requires the pretesting, listing and certification of only the dye, pigment or other color ingredient added to the finished cosmetic prod-

uct, called the "color additive," and does not require pretesting, listing and certification of the finished cosmetic product itself or its non-color ingredients.

The portion of the regulation challenged by the Third Count changes and limits the statutory exemption for hair dyes (R. 52a).

The Fourth Count, the one involved in this petition, challenges the validity of the portion of the regulation which grants FDA inspectors "free access" to cosmetic formulae and processes, with the penalty for denial of such "free access" of suspension of certification and consequent illegality of sale (R. 60a).

Respondents moved to dismiss the complaint for alleged absence of an actual case or controversy required for justiciability, arguing that the claimed excesses of statutory authority and illegality could not be reviewed in an action under the Declaratory Judgment Act or under the Administrative Procedure Act, but could only be asserted as a defense after a specific enforcement proceeding was instituted. The District Court held a justiciable controversy existed as to all four counts, relying in part on *Abbott Laboratories* v. *Celebrezze*, 228 F. Supp. 855 (D. Del. 1964), which had sustained reviewability of challenged FDA regulations pertaining to labeling of drugs (pp. 21a, 23a-24a).

The Court of Appeals for the Third Circuit reversed the *Abbott Laboratories* decision, and held there was lacking an actual case or controversey required for justiciability, and that Congress intended to restrict judicial review to the administrative procedures and direct appeal to the Court of Appeals provided in the Act (352 F. 2d 286). It is from this decision, as already noted, that this Court granted certiorari (No. 39, October Term, 1966).

Respondents then renewed their motion based on such reversal of *Abbott Laboratories* (R. 100a), but this

time also urged that the Act indicated a Congressional "policy of limiting prior judicial review of administrative actions under this statute" (R. 103a), requiring pursuit of the administrative procedures prescribed in the Act, with direct appeal to the Court of Appeals (§§701(e), 706(d) of the Act; 21 U. S. C. §371(e), 376(d)). The District Court adhered to its original decision as to all four counts (p. 30a), and certified the issue for interlocutory appeal under 28 U. S. C. §1292(b) (p. 34a, R. 5a).

On April 13, 1966, the Court of Appeals affirmed as to the First, Second and Third Counts, but, as to the Fourth Count, reversed the District Court's decision as to the reviewability of FDA's assumption of power to obtain "free access" to formulae and processes for finished cosmetic products, and directed dismissal (p. 19a). The Court of Appeals held this portion of the regulation was not reviewable because it "does not of itself demand compliance at the expense of penalties" (p. 19a), but "simply warns the industry that the Commissioner may—not that he inevitably will—consider a refusal to permit such inspection a sufficient cause for suspending certification" (p. 19a). Thus, the decision as to reviewability appears to turn on the form rather than the substance of the regulation. The extent to which this distinction is in conflict with applicable decisions of this Court is shown below (pp. 22-25, *infra*).

FDA, in promulgating the regulation, followed Section 4 of the Administrative Procedure Act (the "APA"), (60 Stat. 238 (1946), 5 U. S. C. §1003), including published notice of proposed rule making (26 F. R. 679, §1003(a)), opportunity for interested persons to participate (§1003 (b)) and publishing the final regulation (28 F. R. 6439, §§1002, 1003(c)). The regulation was adopted by FDA "in the avowed exercise of its rule-making power"

(*Columbia Broadcasting System, Inc.* v. *United States*, 316 U. S. 407, 417 (1942)); "It was final agency action" (*United States* v. *Storer Broadcasting Co.*, 351 U. S. 192, 198 (1956)).

The regulation expands the statutory definition of "color additive" (§201(t) (1), 21 U. S. C. §321(t) (1),—intended to mean only the dye, pigment or other color added to the product,—to include "Lipstick, rouge, eye makeup colors, and related cosmetics intended for coloring the human body" (§8.1(f), p. 42a). It authorizes FDA to suspend certification of color additives,—defined to include such finished cosmetic products,—if denied "free access to all * * * processes, and formulae involved in the manufacture" of such finished cosmetic products* (§8.28(a)(4), p. 42a). Sale after suspension of certification makes the Act's drastic enforcement provisions immediately applicable.

The decision below that the "free access" provision may not now be reviewed because it provides that "the Commissioner may—not that he inevitably will" enforce it (p. 19a), makes an unsound distinction which ignores reality. For the entire background of the regulation makes it clear that the Commissioner intends compliance, that he "inevitably will" exercise his "free access" and that non-compliance will entail the Act's severe penalties.

Background of the "Free Access" Regulation

The original factory inspection provision authorized FDA, after "obtaining permission of the owner," to enter

* The proposed regulation published in the Federal Register, as to which interested persons were invited to present views (26 F. R. 679, Jan. 24, 1961), did not define "color additives" to include such cosmetics so that industry was not then notified that the final regulation would grant FDA "free access to all * * * processes, and formulae" of such cosmetics.

factories manufacturing food, drugs, devices and cosmetics and inspect "all pertinent equipment, finished and unfinished materials, containers, and labeling therein" (52 Stat. 1057, §704). The right to inspect processes and formulae was not granted. In 1953, following *United States* v. *Cardiff*, 344 U. S. 174 (1952), the Act was amended to eliminate the permission requirement (67 Stat. 477). But inspection of processes and formulae was still not granted. According to FDA's Assistant General Counsel:

> "The managers of the bill expressed their opinions that it would not be a reasonable inspection to demand access to formula files * * *." *

FDA subsequently sponsored the "Drug and Factory Inspection Amendments of 1962" (H. R. 11581, 87th Cong., 2d Sess.), whereby it sought access to factories "in which food, drugs, devices, or cosmetics are manufactured," and to inspect "all things therein (including * * * processes * * *)" (Appendix G, pp. 44a-45a).** The accompanying "Section-by-Section Analysis" stated the purpose to "strengthen existing inspection authority" to grant FDA access to "processes" of food, drugs, devices and cosmetics (Hearings, p. 30)..

The Secretary testified that FDA inspectors "are refused access to formula files" and that (Hearings, pp. 67-8):

> "H. R. 11581 would remedy this problem by granting the Food and Drug Administration authority to make complete inspection of all establishments

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* Paper delivered by William W. Goodrich, Assistant General Counsel, FDA, before American Bar Association's Food, Drug & Cosmetic Law Division, Aug. 8, 1962, published in The Business Lawyer, Vol. XVIII, No. 1, Nov. 1962, pp. 203, 204.

** Hearings Before the Committee on Interstate and Foreign Commerce, House of Representatives, 87th Cong., 2d Sess., held June 19, 20, 21, 22; Aug. 20, 21, 22, 23, 1962 (the "Hearings"), p. 11.

producing foods, drugs, devices, or cosmetics. This provision would allow inspection of all * * * processes, * * *."

He further testified as to his existing authority (Hearings, p. 72):

"The Chairman: Are you authorized to look at the formula files?

"Secretary Ribicoff: We are not."

Industry opposition came not only from the cosmetic industry but from the food industry, which was most concerned at the threatened exposure of vital trade secrets.*

Congress enacted the requested "free access" to processes and formulae, but only as to factories "in which prescription drugs are manufactured" (§704 (a), 76 Stat. 792, 21 U. S. C. §374(a), Appendix E, p. 39a). It withheld the authority as to foods, non-prescription drugs, devices and cosmetics. The law, as passed October 10, 1962, dropped

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* A statement by H. Thomas Austern, counsel for the National Canners Association, asserts (Hearings, p. 137):

"THREAT TO TRADE SECRETS

"Unrestricted access to FDA inspectors to files and records of food manufacturers will unnecessarily expose vital trade secrets and will seriously threaten the very existence of those companies that depend upon carefully developed recipes and processing techniques. Recipes and other trade secrets involved in the manufacture of food products are with few exceptions entrusted only to a relatively small number of personnel in each company. It cannot be questioned that trade secrets such as these are valuable property rights that benefit not only the company involved but also the consuming public.

* * * * * *

"Why the public health or safety warrants the further examination of recipes, manufacturing procedures specified, or other trade secrets is difficult to discover. As to the dangers of this power, it must be remembered that today's inspector may tomorrow be the employee of a competitor.

"Factory Inspection" from its title, and was called "Drug Amendments of 1962" (76 Stat. 780).*

To underscore the Amendments' inapplicability to cosmetics, Congress added (76 Stat. at 791, 21 U. S. C. §359):

> "NONAPPLICABILITY TO COSMETICS
>
> "Sec. 509. This chapter, as amended by the Drug Amendments of 1962, shall not apply to any cosmetic unless such cosmetic is also a drug or device or component thereof."

FDA Counsel Goodrich stated, as to FDA access to formulae of all products:**

> "We think the need is real. And we will continue with all our abilities to urge the Congress to meet the need."

Accordingly, in 1963 FDA sponsored H. R. 6788, Section 101 of which was captioned "EXTENSION OF PRESCRIPTION DRUG INSPECTION AUTHORITY TO OTHER DRUGS, FOOD, COSMETICS, AND DEVICES" (Appendix H, p. 46a). The Secretary's transmittal letter, dated May 29, 1963, referred to the "strengthened inspection authority with respect to prescription drugs" which granted access to "processes," and stated that "Similar authority is needed with respect to other products"; that FDA is hampered "when it is denied access to formulas," and that "The enclosed bill would, therefore, extend the inspection authority presently applicable only to prescription drugs to all other products

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If he is, he can hardly be expected to brainwash himself of every recipe, formula, personnel record, or trade secret that he has encountered."

* These amendments and other regulations thereunder as to labeling are the ones involved in *Abbott Laboratories* v. *Celebrezze* (No. 39).

** Business Lawyer, Vol. XVIII, Nov. 1962, p. 207.

covered by the Food, Drug, and Cosmetic Act." (See Appendix I, pp. 48a-50a.) The requested authority was again withheld.

Subsequently, FDA, by the challenged regulation, simply took the power to obtain "free access" to all cosmetic "processes, and formulae." Its accompanying release warned that refusal of such access may cause FDA to refuse to certify the cosmetic product and "thus in effect ban it from the market" (R. 9aa).

FDA's brief below stressed its need for "free access" to cosmetic formulae, making substantially the same argument presented to Congress; namely, that such access was "plainly needful for the effective enforcement of the Act," and that the Commissioner "must have access to the plants where they [the cosmetics] are made" and to cosmetic formulae, since "There is no other way in which the Commissioner" can perform his functions*. Such assertions, coupled with its persistence in seeking the "free access" authority from Congress, makes it unlikely FDA will refrain from exercising the power taken by regulation. It is unrealistic to assume, as the court below did, that the possibility is "remote" because "No one can now say whether the Commissioner will ever make a demand for free access" (p. 19a).

FDA use of "may" rather than "will" can hardly soften the impact on the cosmetic industry of the power it illegally took or its warning it may "ban it [the product] from the market" (R. 9aa).

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* Respondents' original brief in the District Court, undated, and served March 3, 1964, pp. 49, 50.

Similarly, affidavits of Oscar Garth Fitzhugh and Kenneth A. Freeman, of FDA's Bureau of Scientific Standards and Evaluations, sworn to, respectively, May 26, 1964 and May 22, 1964, submitted in support of the "free access" regulation, stated that FDA "must know the exact formula of the product" (Fitzhugh, ¶2),

Reasons for Granting the Writ.

I

The fact this Court granted certiorari in *Abbott Laboratories* v. *Celebrezze* (No. 39) is a significant reason for granting the writ in this case. Though both cases involve the general issue of reviewability of agency regulation by declaratory judgment and under the APA, they present entirely different facets of such issue.

Abbott Laboratories is not a case where FDA took by regulation a power Congress had withheld. Congress had imposed a specific requirement and FDA merely interpreted how such requirement could be satisfied.

The Drug Amendments of 1962 provide that a prescription drug is misbranded unless its established or generic name is "printed prominently" on the label in type half as large as any brand or proprietary name (§502 (e) (1) (B) of the Act; 21 U. S. C. §352(e) (1) (B)). Under the challenged regulation the requirement of "prominently" is satisfied only if the generic name appears each time the brand or proprietary name is used (21 C. F. R. §1.104 (g)(1)). FDA was merely interpreting the word "prominently." The Court of Appeals regarded the regulations as "interpretive regulations which represented the Commissioner's interpretation of the meaning of the Act" (*Abbott Laboratories* v. *Celebrezze*, 352 F. 2d 286, 289).

However, as the District Court in the case at bar stated (p. 33a):

> "But the situation in this case is significantly different. Here the plaintiff contends that: • • • (3) they [the Color Additive Amendments] do not grant FDA access to industry formulae for cosmetic prod-

and that "it is necessary that we have a full disclosure of all the ingredients in any color additive," defined to mean finished cosmetic products (Freeman, ¶4).

> ucts," but that "FDA has issued regulations, purportedly under the authority of the Color Additive Amendments, which would: * * * (3) grant FDA inspectors access to cosmetic formulae. In short, the complaint contains significant allegations of administrative regulations which rather markedly depart from what preliminarily appears to be the plain legislative authority conferred by Congress. * * * this case presents a different issue of 'reviewability' or 'justiciability' than that before the court in *Abbott Laboratories.*"

As the District Court further stated, this case does not involve an issue of "how the regulations are to be interpreted and applied," but "allegations of serious and significant excesses by an executive agency, through the device of final regulations, beyond the powers conferred by Congress upon the agency" (p. 33a). While the Court of Appeals considered *Abbott Laboratories* "not distinguishable on any satisfying basis" (p. 17a), it disagreed with the decision.

It is petitioners' position that, as the District Court held, the two cases present "significantly different" (p. 33a) issues of reviewability,—a fact which warrants certiorari and makes it desirable that both cases be presented to this Court at the same time.

II

With the continued expansion of administrative power and the vast increase in agency regulations, it has become increasingly important to the public, to lower courts and to the agencies affected to have an authoritative definition and clarification of when agency regulations may be reviewed by declaratory judgment and under the APA. Various courts of appeals have expressed differences as to this issue, as exemplified in the Third Circuit by *Abbott*

Laboratories, and in the Court of Appeals for the District of Columbia Circuit by *Danville Tobacco Association* v. *Freeman*, 351 F. 2d 832 (1965), *Helco Products Co., Inc.* v. *McNutt*, 137 F. 2d 681 (1943), and *American President Lines, Ltd.* v. *Federal Maritime Commission*, 316 F. 2d 419 (1963).

The dichotomy is manifest in the decision below where, in passing on four portions of a single regulation which "are interrelated as elements of a common plan of governmental regulation" (p. 27a), the court held three portions reviewable and the fourth not reviewable.

III

An industry is confronted with a regulation violation of which may result in severe penalties,—the same penalties facing the drug industry under the labeling regulation in *Abbott Laboratories*.

The Congressional hearings made clear the harm to industry from disclosure of valuable trade secrets (see pp. 14-15, *supra*). Cosmetic manufacturers expend vast sums to develop new cosmetic formulae and processes. Free access to such formulae would destroy incentive for research and development work. The District Court stated that petitioners' affidavits show that granting "access to all formulae and processes will have an immediate adverse effect upon further research and development of new products" (26a). Respondents did not challenge this.

The cosmetic industry is faced with the identical dilemma as the drug industry, described in petitioners' reply brief in *Abbott Laboratories*.* Here, as in *Abbott Laboratories*, if

* "Petitioners should not be forced to the choice of either complying with regulations believed to be unlawful or running the risk of suffering severe sanctions. Respondents should not be permitted to hold an entire industry at hazard, arbitrarily selecting both the

the cosmetic industry cannot obtain prior review, its choice is either to comply with regulations believed to be unlawful, —and which the District Court stated "rather markedly depart from what preliminarily appears to be the plain legislative authority conferred by Congress'" (33a),—or to gamble whether "may" becomes "inevitably will," and risk having their products banned from the market.

It is insufficient protection to compel a manufacturer to await the inspector. If "free access" is granted to avoid the risk his product will be banned from the market, then he will suffer the very damage, the avoidance of which had caused Congress to deny FDA the requested authority as to foods, cosmetics, devices and non-prescription drugs, and grant it only for prescription drugs. On the other hand, if the manufacturer refuses to grant "free access" to his secret formulae and processes, then, as the FDA release warned, his products can be banned from the market. Sale will entail severe sanctions. Even if he prevails after years of litigation, the damage will have been done. There will have been a long period when his product is off the market,

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companies against which these sanctions will be invoked and the drugs whose marketing will be delayed even if the regulations are ultimately held to be unlawful." (p. 7).

• Winton B. Rankin, then FDA Assistant Commissioner for Planning, testified in his deposition taken in this case on January 22, 1965 that FDA did not have the power under the Act to inspect the formulae of cosmetic manufacturers (p. 689):

> "Q. • • • Does FDA inspect or have authority to inspect the formulas of cosmetic manufacturers? A. No. This [referring to Section 704(a) of the Act] gives no authority to inspect the formulas of cosmetic manufacturers."

Similarly, FDA Deputy Commissioner John L. Harvey, after enactment of both the Color Additive Amendments of 1960 and the Drug Amendments of 1962, referring to certain cosmetics, unequivocally stated that "under the present factory section of the law, we do not have the authority to determine the formulas used" (Business Lawyer, Vol. XVIII, No. 1, November 1962, p. 197).

with loss of profits and competitive position and injury to good will and reputation. This Court has recognized that "The harm to property and business can also be incalculable by the mere institution of proceedings." *Ewing* v. *Mytinger & Casselberry, Inc.*, 339 U. S. 594, 599 (1950).

A person unable to obtain prior judicial review can thus be whipsawed into surrender of his rights and compliance with illegal regulations because the consequences of being right are as disastrous as being wrong.

The Declaratory Judgment Act was particularly designed to cover this very situation, and to assure that persons adversely affected by agency regulations claimed to be illegal need not wait for the axe to fall before obtaining judicial review. The Senate Report on the Act states:

> "The [declaratory judgment] procedure has been especially useful in avoiding the necessity, now so often present, of having to act at one's peril or to act on one's own interpretation of his rights, or abandon one's rights because of a fear of incurring damages" (S. Rep. No. 1005, 73d Cong., 2d Sess., p. 2 (1934)).

Borchard has noted that the declaratory judgment procedure has special application to agency regulations, stating that "Possibly in no branch of litigation is the declaration more useful than in the relations between the citizen and the administration" ("Challenging 'Penal' Statutes by Declaratory Action," 52 Yale L. J. 445 (1943)).

IV

Each reason advanced below to justify the decision that the "free access" regulation is not ripe for review is in conflict with applicable decisions of this Court.

The Court below found unripeness because (pp. 19a-20a):

(a) The challenged regulation "does not of itself demand compliance at the expense of penalties"; "It simply warns the industry that the Commissioner may —not that he inevitably will"—consider denial of free access cause to suspend certification and ban the product from the market;

(b) "No one can now say whether the Commissioner will ever make a demand for free access" to processes or formulae of cosmetics or "whether any manufacturer will ever decline this"; and

(c) It "is not a sufficient basis for declaratory relief" that the risk of "the possible consequences of refusal may induce manufacturers to be more compliant".

Each such reason is in conflict with *Columbia Broadcasting System, Inc.* v. *United States*, 316 U. S. 407 (1942); *Frozen Food Express* v. *United States*, 351 U. S. 40 (1956); and *United States* v. *Storer Broadcasting Co.*, 351 U. S. 192 (1956).

The Columbia Broadcasting System Case:

There the regulations were not issued as "final". Accordingly, they nowhere demanded compliance but, as in the case of the "free access" regulation at bar, required action by the agency. This Court, however, held that the regulations were subject to prior judicial review even though they "are not directed to appellant and do not in terms compel action by it or impose penalties upon it because of its action or failure to act" (316 U. S. at 422). It further held that reviewability was unaffected by the

fact that the regulations were "not directed to any particular person or corporation," or that "their promulgation did not operate of their own force * * *" (p. 417). "Such regulations have the force of law before their sanctions are invoked as well as after" (p. 418).

The argument that the regulations were not reviewable on issuance because described by the agency as "nothing more than the expression of the general policy we will follow" (p. 411, fn. 1) was rejected as "addressed to the form rather than the substance" (p. 419). Similarly, the holding below that the "free access" regulation is not ripe for review because it merely warns that "the Commissioner may—not that he inevitably will" enforce the regulation, is also "addressed to the form rather than the substance."

This Court also held that an administrative order is reviewable where there is risk of penalty, and "it does not cease to be so merely because it is not certain whether the Commission will institute proceedings to enforce the penalty * * *" (pp. 417-8):

> "It is common experience that men conform their conduct to regulations by governmental authority so as to avoid the unpleasant legal consequences which failure to conform entails" (p. 418);
>
> "the expected conformity to them causes injury cognizable by a court of equity" (p. 419).

Reviewability is also unaffected by the fact that the regulation is not couched as a direct grant of access authority but indirectly accomplishes the same result, through the penalty of banning the product from the market, with all the consequences attendant on illegal sale. For, as this Court stated, "it is the substance of what the [agency] has purported to do and has done which is decisive" (p. 416).

The decision below that the regulation is not now ripe for review, and the reasons advanced by the court for such decision, are in direct conflict with the *Columbia Broadcasting System* case.

The Frozen Food Express Case:

The regulation there involved likewise did not "demand compliance" (p. 19a) and Mr. Justice Harlan dissented because it "nowhere commands" compliance (351 U. S. at 45). In fact, that case did not involve a final regulation, but the agency had merely "announced its definition" of a statutory term,—which caused the lower court to hold the order not reviewable (128 F. Supp. 374, 377). This Court, however, sustained reviewability because the order "warns" the industry that violation would involve "the risk of incurring criminal penalties," so that it is not "abstract, theoretical, or academic," but "touches vital interests" of the industry there involved (p. 44),—language which shows the error in the decision below that this "free access" regulation is not reviewable because it "simply warns the industry" (p. 19a).

The Storer Broadcasting Case:

The petitioner Storer, as the dissent noted, did not even allege "present injury of any kind," the challenged regulations "impose no duty," and there was no "possibility of criminal penalties" (351 U. S. at 209, 212, 212 fn. 3). Yet, this Court found "ripeness" for review, since "The process of rulemaking was complete" (pp. 197, 198), and "standing to seek review," since "The Rules now operate to control the business affairs of Storer" (pp. 197, 199).

Similarly, FDA's process of rulemaking was complete with promulgation of its final regulations, and those regula-

tions "now operate to control the business affairs" of the entire cosmetic industry.

This Court,—reaffirming the *Columbia Broadcasting System* case,—again held that regulations are reviewable even though they "did not command [the party seeking review] to do or refrain from doing anything" (p. 198), and " 'do not in terms compel action by it or impose penalties upon it because of its action or failure to act' " (p. 199),—statements totally in conflict with the decision below that there cannot be review because the challenged regulation "does not of itself demand compliance at the expense of penalties" (19a).

In failing to apply to the Fourth Count the principles of the *Columbia Broadcasting System, Frozen Food Express* and *Storer Broadcasting* cases, the Court below enunciated an entirely new principle. This would enable a federal agency by regulation to take power withheld by Congress, to warn industry of the drastic consequences of resisting exercise of such power, and, by merely providing that the power "may" be exercised without asserting it "inevitably will," to prevent prior judicial review through declaratory judgment or under the APA. The court below has provided federal agencies with a ready device for taking power withheld by Congress and preventing effective judicial review.

V

The court below decided an important question of federal law which should be settled by this Court when it denied reviewability by declaratory judgment and under the APA because the challenged regulation authorizes one whose certification has been suspended, with his product

banned from the market, to request a hearing with review by the court of appeals under §§706(d) and 701(f) of the Act, 21 U. S. C. §376d, 371(f) (p. 19a).*

However, such a hearing is limited to "the factual basis for the suspension" (§8.28(b), p. 43a). The factual basis for the suspension would be self-evident, namely, refusal to permit "free access" to secret cosmetic formulae and processes. The hearing would not even present the issue whether FDA had exceeded its statutory authority when it promulgated a regulation granting such "free access." Furthermore, as the District Court stated, "it is scarcely to be thought that judicial review limited to the traditional and narrow scope of whether or not the Commissioner's findings are supported by adequate evidence can supplant the other and broader form of remedy or review available under the Declaratory Judgment Act" (p. 34a).

The decision below that the ostensible remedy for review of the "free access" regulation in an administrative hearing precludes review by declaratory judgment is contrary to the expressed intention of Congress. As the District Court stated, "subsection (f)(6) of Section 701 of the Act underscores the Congressional intention" that the administrative remedy, with direct appeal to the court of appeals, "'shall be in addition to and not in substitution for any other remedies provided by law'" (34a). The House

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* The issue whether existence of such an administrative "remedy" precludes declaratory judgment or a remedy under the APA is also presented in *Abbott Laboratories*, but, as shown above, in connection with a different type of regulation (pp. 17-18, *infra*). The Solicitor General, in opposing certiorari, agreed "there may be substance to petitioners' contention" as to ripeness and a justiciable issue being presented, but took the position that the Act's provisions for administrative hearing and review "demonstrate Congress' intention to limit the instances in which the agency may be forced to defend its issued regulations prior to its enforcement of them" (p. 4).

Report on the original Act,—which fully considered the procedure for administrative review of regulations, with direct appeal to the court of appeals, referred to the Act's saving clause (§701(f)(6), 52 Stat. 1056, 21 USC §371(f)(6)), and stated:

> "There is also saved as a method to review a regulation placed in effect by the Secretary whatever rights exist to initiate a historical proceeding in equity to enjoin the enforcement of the regulation, and whatever rights exist to initiate a declaratory judgment proceeding.
>
> "The special type of review above outlined, where the proceedings are instituted by the individual or business organization affected, will permit an early determination of the validity of the Secretary's action with respect to any proposal for a regulation, amendment, or repeal, and make for prompt certainty as to legal rights." H. R. Rep. No. 2139, 75th Cong., 3d Sess., p. 11 (1938).

The House Report further emphasized that the court can give the fullest possible review and hold a regulation invalid "if for any other reason it was not in accordance with the law" (p. 12):

> "The committee amendment is silent as to any limitations on the court in holding invalid the order of the Secretary. The court is thus left free to exercise its right of review to the full extent that it may constitutionally do so."

Furthermore, in limiting petitioners to an administrative hearing with review by the Court of Appeals, the decision below is in conflict with *Stark* v. *Wickard*, 321 U. S. 288 (1944), where this Court held that agency power "is circumscribed by the authority granted"; that courts are entrusted with the protection of "justiciable individual

rights against administrative action fairly beyond the granted powers"; and that "The responsibility of determining the limits of statutory grants of authority in such instances is a judicial function" (pp. 309-10). Accordingly, this Court sustained judicial reviewability by injunction "in the ordinary courts in the absence of some exclusive alternative remedy" (p. 290). See also, *Heikkila* v. *Barber*, 345 U. S. 229, 232 (1953).

Since this issue is also before this Court in *Abbott Laboratories*, but in the context of a different type of regulation, it can only aid decision of this important question of federal law if the case at bar is simultaneously considered.

VI

(1) The Court below also stated as a reason for not reviewing the "free access" regulation, that "it is impossible to see what declaration a court could properly make" (20a),—a point not raised below in briefs or oral argument. The answer is simple. The declaration would be that the provisions of §§8.1(f) and 8.28(a)(4) of the regulations granting free access to cosmetic formulae and processes are not authorized by the Act and are in excess of statutory authority. In effect, these provisions would be deemed deleted from the regulation.

This presents no greater problem than Congress had when FDA sponsored proposed bills granting access to formulae and processes for all products covered by the Act, and Congress deleted the portion applicable to cosmetics, food, non-prescription drugs and devices, and limited such access to prescription drugs. (See pp. 14-15, *supra*):

At the trial on the merits, the District Court will have ample opportunity, with the benefit of briefs and oral

argument, to explore the kind of declafation which would be proper. It should be no ground for refusing to hear the merits of an action for a declaratory judgment because, without the issue even having been suggested, an appellate court has difficulty at the threshold, and without the merits before it, to see what declaration the District Court could properly make.

(2) It may also be noted that the statement below that "Congress' failure to empower the agency to compel an inspection of processes or formulae" does not show Congressional intent that FDA should not have this power "when the public cannot properly be protected otherwise," (p. 20a) is in conflict with applicable decisions of this Court. This is not a case of mere omission by Congress affirmatively to give FDA access to cosmetic formulae and processes, and where perhaps a possible Congressional intent that FDA should have an implied power can somewhere be found. This is a case where FDA repeatedly asserted it lacked this power and needed it in order properly to protect the public, and requested Congress to grant it, and Congress, after hearings, expressly determined to withhold it as to cosmetics, while granting it as to prescription drugs. Under such circumstances Congress' failure to grant certain power to an agency shows an unequivocal intent that the agency not have the power. *Flora* v. *United States,* 362 U. S. 145, 162-3 (1960); *Boire* v. *Greyhound Corp.,* 376 U. S. 473, 479 (1964); *Continental Casualty Co.* v. *United States,* 314 U. S. 527, 533 (1942); *Carey* v. *Donohue,* 240 U. S. 430, 436-7 (1916).

In *Federal Communications Commission* v. *American Broadcasting Co., Inc.,* 347 U. S. 284, 296 (1954), this Court held that an agency had "overstepped the boundaries" and "exceeded its rule-making power" when, "without success,

it urged Congress to amend the law" and then sought "to accomplish the same result through agency regulations."

VII

The petition presents an important question as to reviewability of federal regulations under the Administrative Procedure Act which should be settled by this Court.

The Court of Appeals, having found jurisdiction under 28 U. S. C. §§1331 and 1337, and having sustained reviewability of the portions of the regulation involved in the first three counts of the complaint, did "not reach the question whether §10 of the Administrative Procedure Act, 5 U. S. C. §1009, constitutes an affirmative grant of jurisdiction with respect to the review of federal administrative action" (3a, fn. 1). However, since it held that the Fourth Count as to "free access" did not present "sufficient basis for declaratory relief" (20a), it would have to consider whether such portion of the regulation could be reviewed under the APA. But it simply ignored the APA.

However, the action as to all counts is clearly authorized by Section 10 of the APA, 5 U. S. C. §1009,—an act "to be given a 'hospitable' interpretation". *Shaughnessy* v. *Pedreiro*, 349 U. S. 48, 51 (1955).

The "free access" regulation is clearly an agency "Rule" and "Agency action" within the meaning of Section 2(c) and (g), 5 U. S. C. §1001(c) and (g). Manufacturers facing compulsory disclosure of valuable trade secrets, at the risk of having their products banned from the market, with sale entailing severe criminal and civil penalties, are clearly persons "adversely affected or aggrieved" by the agency action, as provided in Section 10(a), 5 U. S. C. §1009(a).

As shown above (p. 26), the "remedy" of administrative hearing is inadequate, as limited to "the factual basis for the suspension" (21 CFR §8.28(b)). Accordingly, clearly the "free access" regulation is an act reviewable under Section 10(c), 5 U. S. C. §1009(c), as "final agency action for which there is no other adequate remedy in any court."

Finally, as to the scope of review, Section 10(e), 5 U. S. C. §1009(e), authorizes the court to "(B) hold unlawful and set aside agency action • • • (3) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right".

As stated in *Rusk* v. *Cort*, 369 U. S. 367, 372 (1962), "On their face the provisions of these statutes appear clearly to permit action such as was brought here . . ." Both *Frozen Food Express* (351 U. S. at 42) and *Storer Broadcasting* (351 U. S. at 195) were under the APA, though this Court did not discuss its application.

Since the APA was intended to broaden the scope of judicial review of agency action, this petition presents the opportunity to amplify the application and scope of review of federal regulations under the APA,—an issue of substantial significance to federal agencies and industry.

VIII

Finally, the District Court enunciated a principle applicable to review of agency regulations which the Court of Appeals rejected, but which is so administratively sound that it should be approved by this Court.

The four counts, involving separate portions of a single regulation, are, as the District Court stated, "interrelated as elements of a common plan of governmental regulation". Accordingly, it recognized it was desirable "to

examine all four challenged regulatory provisions together within the context of a single plenary proceeding" (27a).

The interrelationship of the four provisions as "a common plan of governmental regulation" is manifest from the fact that the four provisions were all contained in FDA sponsored legislation which Congress refused to enact.*

There is no remaining issue,—unless respondents should seek a writ as to the first three counts,**—that the portion of the regulation involved in such counts are proper subjects for judicial review by declaratory judgment. It makes no sense, and is administratively undesirable, to have the provisions involved in these three counts now adjudicated by declaratory judgment, but, as to the provision involved in the Fourth Count, to compel industry to await some indefinite future date when validity might or might not be determined, with a sword of Damocles meanwhile hanging. Nor does it make sense to postpone adjudication of the legality of this important regulatory provision until a multitude of individual enforcement proceedings may ensue from denial of free access to cosmetic formulae and processes, with consequent banning of the products from the market.

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* See, e.g., H. R. 11581, H. R. 11582, 87th Cong., 2d Sess., May 3, 1962, Hearings, pp. 2-19; H. R. 6788, 88th Cong., 1st Sess., June 4, 1963.

** On July 6, 1966, the Solicitor General applied for a 30-day extension of time for filing a petition for a writ of certiorari with respect to the decision below on the first three counts. The extension was granted by Mr. Justice Stewart, by order signed July 7, 1966.

Conclusion.

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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EDWARD J. ROSS
One Chase Manhattan Plaza
New York, New York 10005
Attorney for Petitioners

Of Counsel:
BREED, ABBOTT & MORGAN
One Chase Manhattan Plaza
New York, New York 10005